

In the Claims

1. (Currently amended) A composition comprising at least two recombinant adeno-associated viruses (AAV), comprising:

- a first recombinant AAV comprising a first recombinant DNA molecule comprising linked:
  - a first DNA segment comprising a 5'-inverted terminal repeat of AAV;
  - a second DNA segment which does not comprise AAV sequences; and
  - a third DNA segment comprising a 3'-inverted terminal repeat of AAV; and
- a second recombinant AAV comprising a second recombinant DNA molecule comprising linked:
  - a first DNA segment comprising a 5'-inverted terminal repeat of AAV;
  - a second DNA segment which does not comprise AAV sequences and which second DNA segment is different than the second DNA segment of the first recombinant DNA molecule; and
  - a third DNA segment comprising a 3'-inverted terminal repeat of AAV, wherein one recombinant AAV comprises a *cis*-acting heterologous transcriptional regulatory element and the other recombinant AAV comprises an open reading frame encoding a therapeutic gene product, and wherein the *cis*-acting heterologous transcriptional regulatory element regulates expression of the open reading frame in a host cell contacted with the first and second rAAVs.

2. (Withdrawn) The composition of claim 1 further comprising a delivery vehicle.

3. (Withdrawn) The composition of claim 2 where the vehicle is a pharmaceutically acceptable carrier.

4. (Currently amended) The composition of claim 1 wherein the second DNA segment of the first recombinant DNA molecule comprises a portion of an the open reading frame operably linked to a promoter but not a heterologous promoter.

*Cont'd.*

5-7. (Canceled)

8. (Withdrawn) The composition of claim 1 wherein the second DNA segment of the first recombinant DNA molecule comprises an enhancer.

9. (Currently amended) The composition of claim 1 wherein the second DNA segment of the first recombinant DNA molecule comprises a heterologous promoter.

10. (Currently amended) The composition of claim 8-~~or~~9 1 wherein the second DNA segment of the second recombinant DNA molecule comprises ~~at least a portion of an~~ the open reading frame but not a heterologous promoter.

11. (Currently amended) The composition of claim 10 wherein the second DNA segment of the ~~second~~ first recombinant DNA molecule ~~further~~ comprises a heterologous promoter ~~operably linked to the open reading frame~~.

12-18. (Canceled)

19. (Currently amended) A recombinant adeno-associated viral vector comprising at least one cis-acting heterologous transcriptional regulatory element functional in a host cell, which vector regulates, in the host cell, expression of a therapeutic gene in a second recombinant adeno-associated viral vector.

20. (Original) The vector of claim 19 wherein the element is a promoter.

21. (Withdrawn) The vector of claim 19 wherein the element is an enhancer.

22. (Canceled)

23. (Currently amended) A plasmid comprising the vector of claim 18, 19 or 22.

24. A host cell contacted with the composition of claim 1.

25. A host cell contacted with at least two recombinant AAV,  
wherein a first recombinant AAV comprises a first recombinant DNA molecule  
comprising linked:

- i) a first DNA segment comprising a 5'-inverted terminal repeat of AAV;
- ii) a second DNA segment which does not comprise adeno-associated viral sequences; and
- iii) a third DNA segment comprising a 3'-inverted terminal repeat of AAV;  
and

wherein a second recombinant AAV comprises a second recombinant DNA  
molecule comprising linked:

- i) a first DNA segment comprising a 5'-inverted terminal repeat of AAV;
- ii) a second DNA segment which does not comprise adeno-associated viral sequences and which second DNA segment is different than the second DNA segment of the first recombinant DNA molecule; and
- iii) a third DNA segment comprising a 3'-inverted terminal repeat of AAV.

26. A method to transfer recombinant DNAs to a host cell, comprising:  
contacting the host cell with at least two recombinant AAV,  
wherein a first recombinant AAV comprises a first recombinant DNA  
molecule comprising linked:

- i) a first DNA segment comprising a 5'-inverted terminal repeat of AAV;
- ii) a second DNA segment which does not comprise adeno-associated viral sequences; and
- iii) a third DNA segment comprising a 3'-inverted terminal repeat of AAV;  
and

wherein a second recombinant AAV comprises a second recombinant DNA molecule comprising linked:

- i) a first DNA segment comprising a 5'-inverted terminal repeat of AAV;
- ii) a second DNA segment which does not comprise adeno-associated viral sequences and which second DNA segment is different than the second DNA segment of the first recombinant DNA molecule; and
- iii) a third DNA segment comprising a 3'-inverted terminal repeat of AAV

27. (Withdrawn) A method to transfer and express a polypeptide in a host cell comprising contacting the host cell with the composition of claim 1.

28. (Withdrawn) The method of claim 26 or 27 wherein the second DNA segment of the first recombinant DNA molecule comprises a portion of an open reading frame operably linked to a promoter.

29. (Withdrawn) The method of claim 28 wherein the first recombinant DNA molecule comprises a splice donor site 3' to the open reading frame.

30. (Withdrawn) The method of claim 29 wherein the second DNA segment of the second recombinant DNA molecule comprises the remainder of the open reading frame which together with the second DNA segment of the first recombinant DNA molecule encodes a full-length polypeptide.

31. (Withdrawn) The method of claim 30 wherein the second DNA segment of the second recombinant DNA molecule comprises a splice acceptor site 5' to the remainder of the open reading frame.

32. (Withdrawn) The method of claim 26 or 27 wherein the second DNA segment of the first recombinant DNA molecule comprises an enhancer.

33. (Withdrawn) The method of claim 26 or 27 wherein the second DNA segment of the first recombinant DNA molecule comprises a promoter.

34. (Withdrawn) The method of claim 32 wherein the second DNA segment of the second recombinant DNA molecule comprises at least a portion of an open reading frame.

35. (Withdrawn) The method of claim 33 wherein the second DNA segment of the second recombinant DNA molecule comprises at least a portion of an open reading frame.

36. (Withdrawn) The method of claim 34 wherein the second DNA segment of the second recombinant DNA molecule further comprises a promoter operably linked to the open reading frame.

37. (Withdrawn) The method of claim 35 wherein the second DNA segment of the second recombinant DNA molecule further comprises a promoter operably linked to the open reading frame.

38-40. (Canceled)

41. (Withdrawn) The method of claim 26 or 27 wherein the second DNA segment of the first recombinant DNA molecule further comprises DNA encoding a protein that binds to the origin of replication.

42. (Withdrawn) The method of claim 41 wherein the second DNA segment in the second recombinant DNA molecule comprises a portion of an open reading frame.

43. (Withdrawn) The method of claim 41 wherein the second DNA segment in the second recombinant DNA molecule further comprises a promoter operably linked to the open reading frame.

44-45. (Canceled)

46. (Previously added) The composition of claim 1 wherein the second DNA segment of one of the vectors comprises a heterologous transcriptional regulatory element.

47. (Withdrawn) The host cell of claim 25 wherein the second DNA segment of one of the vectors comprises a heterologous transcriptional regulatory element.

48. (Withdrawn) The method of claim 26 or 27 wherein the second DNA segment of one of the vectors comprises a heterologous transcriptional regulatory element.

49. (Withdrawn) A method to enhance the expression of a polynucleotide in a host cell, comprising: contacting a host cell comprising a recombinant AAV vector comprising a polynucleotide segment which encodes a polypeptide, with a composition comprising a further recombinant AAV vector corresponding to the vector of claim 19 in an amount which enhances expression of the polynucleotide.

50. (Withdrawn) A method to enhance the expression of a polynucleotide in a host cell, comprising: contacting a host cell comprising a recombinant AAV vector corresponding to the vector of claim 19, with a composition comprising a further recombinant AAV vector comprising a polynucleotide segment which encodes a polypeptide, in an amount which enhances expression of the polynucleotide.

51. (Withdrawn) A method to enhance the expression of a polynucleotide in a host cell, comprising: contacting a host cell with a recombinant AAV vector corresponding to the vector of claim 19 and a further recombinant AAV vector comprising a polynucleotide segment which encodes a polypeptide, in an amount which enhances expression of the polynucleotide in the cell.

52. (Withdrawn) The method of claim 49 or 50 wherein the composition further comprises a delivery vehicle.

53. (Withdrawn) The method of claim 52 wherein the delivery vehicle is a pharmaceutically acceptable carrier.

54. (Withdrawn) The method of claim 49, 50 or 51 wherein heterologous transcriptional regulatory element in the recombinant AAV corresponding to the vector of claim 19 is a promoter.

55. (New) The composition of claim 1 wherein the second DNA of the second recombinant DNA molecule comprises a heterologous promoter.

56. (New) The composition of claim 55 wherein the second DNA of the first recombinant DNA molecule comprises the open reading frame.

57. (New) The composition of claim 1 wherein the two recombinant AAVs do not contain a heterologous splice site.

57. (New) The composition of claim 1 wherein the two recombinant AAVs do not contain a heterologous splice site. dupl.?

58. (New) The vector of claim 19 wherein the recombinant adeno-associated viral vector comprising at least one *cis*-acting heterologous transcriptional regulatory element and the second recombinant adeno-associated viral vector do not contain a heterologous splice site.